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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yasuo Hayashi

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EXAMINER

LEA, CHRISTOPHER RAYMOND

ART UNIT

PAPER NUMBER

1619

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,423	Applicant(s) HAYASHI ET AL.	
	Examiner Christopher R. Lea	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009 and 01 May 2009 and 05 May.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/JP03/15338.

Receipt of Amendments/Remarks filed on May 1 & 5, 2009, is acknowledged. In response to Non-final office action dated October 16, 2008, applicant canceled claims 1-38, added new claims 39-76 and amended claims 39, 49, 56, 62, & 69. Claims 39-76 are pending. Claims 39-76 are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. All new rejections applied have been necessitated by applicant's amendment to the claims. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 39-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roreger et al. (WO document 02/51815 (German) using US Patent 6,818,087 as translation) in view of Nogami (WO document 02/87622 (Japanese) using US PreGrant Publication 2004/0137040 as translation).

Applicant claims

Applicant claims a method and apparatus for manufacturing a multilayer edible film composition for administering an active agent.

Determination of the scope and content of the prior art (MPEP 2141.01)

Roreger et al. teach, as a whole, a method and apparatus for manufacturing a layered film composition containing an active agent.

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Claims 39, 49, 56, & 62: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach the base layers provided on both sides with protective layers and peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49). Determination of the arrangement of the delaminating apparatus and of the number of layers to be removed is within the purview of the skilled artisan. Repeating the steps of laminating another layer on and delaminating its protective cover would also be within the purview of a skilled artisan. Roreger et al. teach the base materials being provided on stock rolls (column 4, lines 37-49), which means the step of winding the layers onto a roll would be necessarily carried out. Determining the size of the delamination roll (winder) is within the purview of the skilled artisan.

Claims 40, 50, 51, 57, 58, & 63: Roreger et al. teach that the protective layers are treated with silicone to be rendered detachable (column 4, lines 37-49). Determining which sides of which compositions would receive this treatment is within the purview of the skilled artisan.

Claims 41, 52, 58, & 65 : Roreger et al. teach the pressure of the laminating step is 2 to 10 bars (0.2 to 1 MPa) which is inside the claimed range (column 5, lines 62-65).

Claims 42, 44, 45, 53, 59, & 66: Roreger et al. teach thermally conditioning the laminating equipment (column 5, lines 60-61) to achieve a desired viscosity in the base material. Though Roreger et al. do not teach a temperature at which the laminating is

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accomplished, it would be within the purview of the skilled artisan to determine the optimum temperature to insure binding by routine experimentation.

Claim 43: Roreger et al. teach that after binding the layered composition is cooled to a temperature of 3 to 10°C (column 6, lines 55-57).

Claims 46, 54, 60, & 67: Roreger et al. teach a base material that is 36 and 80 μm thick (example, column 7, lines 1-16).

Claims 47, 55, 61, & 68: Roreger et al. teach that the base materials are self-supporting laminate films (example, column 7, lines 1-16).

Claim 48: Roreger et al. teach removing the protective layers (column 4, lines 37-49). Determining when to remove the protective layer and which layers to remove is within the purview of the skilled artisan.

Claims 69-71: Roreger et al. teach uniting two base material layers together under pressure (column 5, lines 65 through column 6, line 1) using pressure rollers (element 13 in figure 1). Roreger et al. teach the base layers provided on both sides with protective layers and peeling (delaminating) a protective layer, such as paper, plastic (resins) or textiles, off of the base material layers (column 4, lines 37-49) and onto winding rolls (element 6 in figure 1). Determining the size and position of the delamination roll (winder) is within the purview of the skilled artisan.

Claim 72: Roreger et al. teach the unwinding rolls (elements 1a and 2a in figure 1) and the winding rolls (elements 5 & 6), and it would be within the purview of the skilled artisan to determine the size of the rolls through routine experimentation.

Claim 73-76: Roreger et al. teach that the composition can be cut after bonding (column 6, lines 58-60). The claims further describe a system for receiving the finished product and storing on a plurality of wheels. Roreger et al. teach a single wheel to receive the product (see figure 1, unlabeled element below 14) and the duplication of this element for each of the cut-down film compositions would be obvious to the skilled artisan.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between Roreger et al. and the instant claims is that Roreger et al. do not expressly teach edible films and the methods of making the drug-containing films. This deficiency in Roreger et al. is cured by the teachings of Nogami.

Nogami teaches, as a whole, a layered edible film composition for administering an active agent.

Claims 39-76: Nogami teaches making the layers by applying (spray coating) a solution onto a film and drying it (manufacturing example 1, paragraph 109). Nogami teaches the drug-containing layer is made of an edible polymer including cellulose and cellulose derivatives preferably hydroxypropylcellulose and hydroxypropylmethylcellulose phthalate (paragraph 54). Nogami teaches that the multilayered composition can be made by thermally fusing two medicinal agents together through and intermediate adhesive layer (paragraph 103 and figure 11). Nogami et al. teach that many of the same polymers can function as both the base for drug-containing layer and adhesive intermediate layer (paragraph 51 and 84), therefore the layers could be

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integrated to form a single layer adhesive/drug-containing layer, especially since Nogami teaches the possibility of two drug layers being adjacent (paragraphs 49 & 81). Though Nogami teaches a composition having a water-swellaable layer between the film and the drug-containing layer (paragraph 109), the elimination of this layer would have been obvious to the skilled artisan if this function is not desired.

As to the claimed non-permeation of one layer into another, where the claimed and prior art products are substantially identical in structure or composition, or are produced by substantially identical processes, a *prima facie* case of obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed non-permeation of one layer into another, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the edible layered active agent composition of Nogami by a modified laminate composition-producing method and apparatus as taught

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by Roreger et al. and produce the instant invention. The skilled artisan would have been motivated to make the layered film compositions in this manner because Nogami suggests forming multilayer film compositions by making two halves of the composition and thermally fusing them under pressure (paragraph 108).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in making the edible layered active agent composition of Nogami by a modified laminate composition-producing method and apparatus as taught by Roreger et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Response to Arguments

5. Applicant's arguments filed May 5, 2009, have been fully considered but they are not persuasive. Applicant argues that Roreger et al. do not teach forming an active agent-containing layer on a film. This is not found persuasive as the cited references both teach polymer layers formed on support films (Roreger et al. at column 4, lines 35-42 and Nogami at paragraph 109), and Nogami specifically teaches agent-containing layers formed on the film, albeit not directly (paragraph 109). Applicant argues that

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neither Roreger et al. nor Nogami teach removing only one of the resin films after the layers are sandwiched. This is not persuasive as both Roreger et al. (column 4, lines 48-50) and Nogami (paragraph 113) teach removing a support film. The determination of when to remove the film and which films to remove are certainly within the purview of the skilled artisan. Applicant further argues that Nogami does not teach combining the layers by press rollers. This not persuasive because Nogami does teach heat fusing the layers under pressure (paragraph 108), and Roreger et al. teach press rollers (element 13). Applicant argues that Roreger et al. do not teach adding a third layer. This is not found persuasive as Nogami embodies the concept of having multiple active agent-containing layers (figure 5 and paragraph 49). Applicant argues that the neither Roreger et al. nor Nogami teach the non-diffusive nature of the layer's ingredients. This is not found persuasive (and has been addressed in the 103 section) as the non-diffusive nature depends on the materials used, Nogami teaches using some of the same polymers as applicant, and identical chemical compounds cannot have non-identical properties.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, it is the examiner's assertion that the cited references do teach all the elements of the claimed methods and apparatus, albeit not in the claimed arrangements, and that the elements can be rearranged, duplicated, and/or deleted in a

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manner that would have been obvious to the skilled artisan to produce the claimed invention.

Applicant's overall argument is that the cited references do not teach all the elements of the claimed invention. This is not persuasive because between them, Nogami and Roreger et al. teach spraying a solution and drying it to form a layer on a support backing, winding the layer up, unwinding, delaminating the support backing, pressure bonding the layers, and slicing the bonded layers -- all elements of the claimed methods and apparatus. The rearrangement and duplication of parts (while retaining their functions) have been established as obvious modifications (MPEP § 2144.04 VI.B & C). The elimination of an element if its function is not desired has likewise been found to be obvious (MPEP § 2144.04 II.A). In the absence of some unexpected result, the examiner concludes that the claimed invention is a collection of known elements, with each element performing its ordinary function, arranged in a manner that would have been obvious to one of ordinary skill in the art.

Conclusion

Claims 39-76 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Fri 8:00-4:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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CRL

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616